Remarks/Arguments:

This amendment is accompanied by a Request for Continued Examination. These remarks are directed to the Office Action dated January 25, 2010. Citations to paragraphs of the specification refer to the published application, US 2006/0239884.

Claims 1-15, 17, and 19-22 are pending. Claim 1 is amended to clarify that the composition comprises an aqueous dispersion or precipitate of separated, highly crystalline calcium phosphate platelets, wherein at least 80% of the platelets have the described dimensions. Claims 10 and 11 are amended to clarify that the method is for preparing an aqueous dispersion of separated, highly crystalline calcium phosphate platelets, wherein at least 80% of the platelets have the described dimensions. Support for these amendments is found in the specification at paragraphs [0016], [0019], [0022], [0025], [0049]-[0050], [0057]-[0059], [0072], [0090], [0094], and original claim 8. No new matter is added by these amendments.

Claim 8 is cancelled. Claims 2, 3, 5, 7, and 9 depend from claim 1 and contain all the elements of claim 1.

I. 35 USC Section 102(b)

"Because the hallmark of anticipation is prior invention, the prior art reference - in order to anticipate under 35 U.S.C. § 102 - must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2007), quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

Claims 1-3, 5, and 7-9 stand rejected under Section 102(b) as anticipated by Itoi (US 6,159,437). The Office Action states that Itoi discloses a composition comprising separated calcium phosphate platelets that exhibit apatite structure and have dimensions of 30-300 nm by 10-100 nm

(Office Action, page 2, paragraph 2). Claim 8 is cancelled. Claim 1 is amended as described above. Claims 2, 3, 5, 7 and 9 depend from claim 1 and contain all of the elements of claim 1.

Applicant traverses this rejection because Itoi does not disclose an aqueous dispersion or precipitate of separated calcium phosphate platelets. Itoi is directed to preparing a slurry of apaptite particles dispersed in an organic solvent (Itoi, col. 2, lines 10-14; col. 3, lines 37-44). Itoi teaches a method of making "primary" hydroxyapatite particles having a length between 30-300 nm and a width between 10-100 nm (Itoi, col. 3, lines 25-29), but Itoi does not disclose an aqueous dispersion wherein at least 80% of the platelets are between 250-800 nm in length. In addition, Itoi also states that these primary particles aggregate and form apatite particles of 10-100 μm in size ("secondary" particles) (Itoi, col. 3, lines 33-35; col. 4, lines 2-3).. Itoi teaches reducing the size of the secondary particles by milling. Milling reduces aggregate size, but does not result in separation of the calcium phosphate platelets, because the average particle size after milling is 1 μm (Itoi, col. 4, lines 4-5). Therefore, because Itoi does not disclose all elements of the claims arranged as in the claims, Itoi does not anticipate claims 1-3, 5, 7, or 9.

Claims 1 and 2 stand rejected as anticipated by Lee (WO 2000/015194). The Office Action states that Lee discloses a composition of separated calcium phosphate platelets having apatite structure and a length of 300 nm (Office Action, pages 3-4, paragraph 9). Claim 1 is amended as described above. Claim 2 depends from claim 1 and contains all the elements of claim 1.

Applicant traverses this rejection because Lee does not disclose separated, highly crystalline calcium phosphate platelets. Lee teaches a preparation of calcium phosphate, wherein at least 75% of the calcium phosphate has an **amorphous**, not crystalline, structure (Lee, page 4, lines 18-19; page 6, lines 19-23). The size of the primary calcium phosphate particles is 5-150 nm, but the primary particles form aggregates and are not separated. Although not explicitly shown in the cited Lee reference, the reference incorporates by reference documents describing methods for making calcium phosphates suitable for the invention. Each of these documents has a figure and figure

legend demonstrating that the calcium phosphates prepared by Lee are aggregated and not separated. These are US 6,117,456 (Figure 1, Description of Fig. 1: "nanometer size grains in clusters"); US 5,683,461 (Figure 1, Description of Fig. 1: "nanometer size grains in clusters"); and 5,783,217 (col. 8, lines 24-26, "Powders having a particle size in the range of about 250 μm to about 0.5 mm are contemplated."). In addition, Lee does not disclose and aqueous dispersion of calcium phosphate platelets. Lee discloses preparations of gels, pastes, pellets, and powders of calcium phosphate platelets (Lee page 24, lines 8-24; Examples 1-17. Therefore, because Lee does not disclose all elements of the claims arranged as in the claims, Lee does not anticipate claims 1 or 2.

Claims 1 and 2 stand rejected as anticipated by Roeder (US 2003/0031698). The Office Action states that Roeder discloses a composition of separated calcium phosphate platelets of monetite structure having a length of between 1 and 500 nm (Office Action, page 4, paragraph 12).

Applicant traverses this rejection because Roeder does not disclose an aqueous dispersion or precipitate of separated calcium phosphate platelets. Roeder discloses anisometric calcium phosphate particles within a thermoplastic polymer matrix or a calcium phosphate-based matrix, such as cement, for use in orthopedic implants (Roeder, paragraphs [0010], [0027], [0029], [0030]). Roeder states that "dispersed" does not preclude contact between the particles, suggesting that the particles are not "separated" (Roeder, paragraph [0037]). Examples 1-6, describe the calcium phosphate particles as having an average particle size of 2-3 μm or an average length of 20 μm (Roeder, paragraphs [0065], [0070], Figure 4A and 4B, Table 2), demonstrating that Roeder does not disclose "separated" calcium phosphate platelets. In addition, Roeder does not disclose an aqueous dispersion wherein at least 80% of the platelets are between 250-800 nm in length. Therefore, because Roeder does not disclose all elements of the claims arranged as in the claims, Roeder does not anticipate claims 1 or 2.

For at least these reasons, Applicants request that the rejection of claims 1-3, 5, 7, and 9 under Section 102(b) be withdrawn.

II. 35 USC Section 103(a)

The Office Action reasserts each of the above Section 102(b) rejections under Section 103(a), because "anticipation is the epitome of obviousness" (Office Action, paragraphs 7, 10, 13). Applicant traverses this rejections for the following reasons. This particular relationship between anticipation and obviousness originates in *In re Fracalossi*, 681 F.2d 792 (CCPA 1982). The original statement of Judge Markey was "[l]ack of novelty is the ultimate of obviousness," (*In re Fracalossi*, page 794). What the expression means is that an invention cannot be anticipated and not also be obvious (*Id.*). Therefore, Applicants submit that the expression is being improperly applied in the Office Action. The Office Action fails to delineate any "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," (*KSR Internat'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977 (CA Fed. 2006)). As discussed above, Applicants' invention is not anticipated by the cited art, and accordingly, cannot be *per se* obvious over the cited art. Therefore, Applicants request that the claim rejections under Section 103(a) over Itoi, Lee, and Roeder individually be withdrawn.

To establish a prima facie case of obviousness, the combination of references cited must teach or suggest every element of the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed Cir. 1983).

Claims 10, 12-15, and 17 stand rejected under Section 103(a) as unpatentable over Kumta (US 7,247,288) in view of Itoi. The Office Action states that Kumta teaches a method for preparing separated nanocrystalline calcium phosphate platelets and Itoi discloses a composition of separated calcium phosphate platelets having apatite structure. The Office Action states that it would have been obvious to one of ordinary skill in the art to modify the process of Kumta with the platelet size and heat treatment of Itoi to obtain the platelets described by Itoi (Office Action, page 5, paragraph

16; page 7, paragraph 24; page 8, paragraph 25). Applicant traverses this rejection for the following reasons.

The Office Action states that the teachings of Kumta and Itoi can be combined to produce a method for preparing the platelets described by Itoi. However, the Office Action does not state why it would be obvious to combine the teachings of Kumta and Itoi to produce a method for preparing the composition claimed by Applicants. Therefore, the FOA has failed to establish a prima facie case of obviousness for claims 10, 12-15, and 17 over the combination of Kumta and Itoi.

Kumta teaches a method for making hydroxyapatite particles, which aggregate to form "agglomerates" having a size of greater than 2-5 mm (Kumta, Figure 5 and col. 5, legend to Fig. 5, col. 17, lines 19-22, "The microstructure of the as-prepared Hydroxyapatite powder shows nano-sized (<100 nm) Hydroxyapatite crystallites aggregated into agglomerates (about 2-5 mm)."). Thus, Kumta teaches a method to prepare hydroxyapatite particles that aggregate, but does not teach a method to prepare separated calcium phosphate platelets as required by Applicants' claims. In addition, Kumta does not disclose a method to produce an aqueous dispersion wherein at least 80% of the calcium phosphate platelets are between 250-800 nm in length.

Furthermore, Kumta's method utilizes reaction conditions with a very high pH of 11-12, whereas Applicant's claimed method utilizes relatively low pH conditions of 4-6. The Office Action states that pH is a "result effective variable" and that developing a suitable solution pH is within the skill of one in the art (Office Action, page 7, paragraph 23). However, Kumta explicitly teaches the necessity of including NaOH in the reaction solution to maintain a high pH during the initial reaction between the phosphate and the calcium salt. Kumta discloses that dropping to below pH 9 results in calcium-deficient hydroxyapatite, which is inferior and unstable at elevated temperatures (Kumta, col. 15, lines 15 to col. 16, line 36). The high pH method was deliberately selected by Kumta to prepare hydroxyapatite for use in gene delivery (Kumta, Example 2, col. 18, lines 16-17). Therefore,

Kumta specifically teaches away from the preparation and use of deficient apatite and teaches away from Applicant's low pH method for preparing monetite and deficient apatite platelets.

Itoi teaches a method for milling aggregated apatite particles in an organic solvent to reduce the size of the aggregations. Itoi's experimental examples utilize commercially available hydroxyapatite, which contains aggregates of apatite particles. Itoi does not elaborate specific conditions for making apatite particles, but only states that it can be done by known reactions (Itoi, col. 2, line 60 through col. 3, line 2), and at particular temperatures (Itoi, col. 3, lines 28-32), to produce aggregates of apatite particles (Itoi, col. 3, lines 33-35). As discussed above, even after the milling process, Itoi's calcium phosphate platelets remain aggregated and are not separated. As discussed above, Itoi teaches the use of an organic solvent, and does not disclose a method to produce an aqueous dispersion wherein at least 80% of the platelets are between 250-800 nm in length.

Therefore, neither Kumta nor Itoi teach or suggest a method to produce an aqueous dispersion of separated calcium phosphate platelets as required by Applicant's claims, and this combination of references fails to teach all elements of the claims at issue. Furthermore, one of skill in the art would not have a reasonable expectation that combining Kumta with Itoi would yield Applicant's method for preparing separated platelets, because Kumta teaches the importance of maintaining high pH during the reaction, Itoi is silent as to the range or effect of pH in the preparation of apatite particles, and Applicant's method utilizes a pH range of 4-6.

For at least these reasons, the combination of Kumta and Itoi fails to render claims 10, 12-15, and 17 unpatentable as obvious.

Claims 11 and 19-22 stand rejected under Section 103(a) as unpatentable over Kumta in view of Roeder. The Office Action states that Kumta discloses a method for preparing separated nanocrystalline calcium phosphate platelets having apaptite structure and Roeder discloses a

composition comprising calcium phosphate platelets having monetite structure. According to the Office Action, it would be obvious to one of ordinary skill in the art to modify the process of Kumta with the platelets of Roeder to obtain a process for producing platelets useful in composite biomaterials. (Office Action, page 8, paragraph 27). Applicant traverses this rejection for the following reasons.

Claims 11 and 19-22 are not directed to the production of platelets useful in composite biomaterials, but are directed to a method of producing an aqueous dispersion of separated calcium phosphate platelets, wherein at least 80% of the platelets are between 250-800 nm in length. As discussed above, Kumta teaches away from Applicants' claimed method and claimed composition and does not disclose or suggest a method to prepare an aqueous dispersion of separated calcium phosphate platelets wherein at least 80% of the platelets are between 250-800 nm in length. In addition, Kumta's method involves adding a phosphate/NaOH solution directly to a calcium chloride solution (Kumta, col. 15, lines 1-2), whereas in claim 11, the phosphate solution must be added slowly, over a period of time between 30 minutes and 4 hours, to a calcium solution.

Roeder cannot compensate for the claim elements not found in Kumta. Roeder discloses the incorporation of anisotropic calcium phosphate particles into a thermoplastic polymer or a calcium phosphate composition, such as cement, as discussed above, and thus does not disclose preparation of an aqueous dispersion of separated calcium phosphate platelets. Roeder teaches a method of making hydroxyapatite "whiskers" that combines calcium, phosphate, and a chelating acid such as lactic, formic, or glacial acetic acid (Roeder paragraph [0057]). In the method taught by Roeder calcium is added directly to a solution of the phosphate and chelating acid. Thus, Roeder also fails to disclose the slow addition of phosphate that is required by claim 11. Therefore, the combination of Kumta and Roeder fails to disclose all elements of claims 11, and 19-22 and does not render these claims unpatentable as obvious.

For the reasons set forth above, Applicant submits that claims 10-15, 17, and 19-22 are patentable over the cited art and request that the rejections of these claims be withdrawn.

In view of the amendments to the claims and the foregoing remarks, the pending claims are believed to be allowable over the prior art of record. Accordingly, it is respectfully requested that this application be allowed and a Notice of Allowance be issued. If the Examiner believes that a telephone conference with Applicants' attorney would be advantageous to the disposition of this case, and in particular if a terminal disclaimer is required for allowance, the Examiner is cordially requested to telephone the undersigned. If the Examiner has any questions in connection with this paper, or otherwise if it would facilitate the examination of this application, please call the undersigned at the telephone number below.

Because the reasons above are sufficient to traverse the rejection, Applicants have not explored, nor do they now present, other possible reasons for traversing such rejections. Nonetheless, Applicants expressly reserve the right to do so, if appropriate, in response to any future Office Action.

A Request for Continued Examination and the associated fee is filed herewith. A Notice of Appeal had previously been filed in this matter on April 22, 2010. Accordingly, no additional fee is believed to be required. In the event the Commissioner of Patents and Trademarks deems additional fees to be due in connection with this application, Applicant's attorney hereby authorizes that such fee be charged to Deposit Account No. 50-3569.

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Respectfully submitted,

Eric E. Grondahl
Registration No. 46,741
Attorney for Applicants

PTO Correspondence Address:
McCarter & English LLP
City Place I
185 Asylum Street
Hartford, CT 06103
(860) 275-6704 - Phone
(860) 724-3397 - Fax